

**STATE OF CALIFORNIA
DEPARTMENT OF INDUSTRIAL RELATIONS
Division of Workers' Compensation**

NOTICE OF PROPOSED RULEMAKING

**Subject Matter of Regulations: Workers' Compensation – Official Medical Fee Schedule:
Inpatient Hospital Fee Schedule**

**TITLE 8, CALIFORNIA CODE OF REGULATIONS
Sections 9789.20 et seq.**

NOTICE IS HEREBY GIVEN that the Administrative Director of the Division of Workers' Compensation, pursuant to the authority vested in her by Labor Code sections 59, 133, 4603.5, 5307.1 and 5307.3 proposes to revise sections 9789.20 through section 9789.22, and adopt section 9789.25 in Article 5.3 of Division 1, Chapter 4.5, Subchapter 1, of title 8, California Code of Regulations, relating to the Official Medical Fee Schedule – Inpatient Hospital Fee Schedule.

PROPOSED REGULATORY ACTION

The Division of Workers' Compensation, proposes to amend Article 5.3 of Division 1, Chapter 4.5, Subchapter 1, of Title 8, California Code of Regulations, by adopting regulations commencing with section 9789.20:

- 1. Amended section 9789.20 Inpatient Hospital Fee Schedule: General Information for Inpatient Hospital Fee Schedule – Discharge On or After July 1, 2004**
- 2. Amended section 9789.21 Definitions for Inpatient Hospital Fee Schedule**
- 3. Amended section 9789.22 Payment of Inpatient Hospital Services**
- 4. Proposed section 9789.25 Federal Regulations, Federal Register Notices, and Payment Impact File by Date of Discharge**

AN IMPORTANT PROCEDURAL NOTE ABOUT THIS RULEMAKING:

The Inpatient Hospital Fee Schedule component of the Official Medical Fee Schedule "establish(es) or fix(es) rates, prices, or tariffs" within the meaning of Government Code section 11340.9(g) and is therefore not subject to Chapter 3.5 of the Administrative Procedure Act (commencing at Government Code section 11340) relating to administrative regulations and rulemaking.

This rulemaking proceeding to amend the Inpatient Hospital Fee Schedule is being conducted under the Administrative Director's rulemaking power under Labor Code sections 133, 4603.5, 5307.1 and

5307.3. This regulatory proceeding is subject to the procedural requirements of Labor Code sections 5307.1 and 5307.4.

This Notice and the accompanying Initial Statement of Reasons are being prepared to comply with the procedural requirements of Labor Code section 5307.4 and for the convenience of the regulated public to assist the regulated public in analyzing and commenting on this non-APA rulemaking proceeding.

PUBLIC HEARING

A public hearing has been scheduled to permit all interested persons the opportunity to present statements or arguments, either orally or in writing, with respect to the subjects noted above. The hearing will be held at the following time and place:

Date: Tuesday, January 25, 2011
Time: 10:00 a.m. to 5:00 p.m. or conclusion of business
Place: Elihu M. Harris State Building, Auditorium
1515 Clay Street,
Oakland, CA 94612

In order to ensure unimpeded access for disabled individuals wishing to present comments and facilitate the accurate transcription of public comments, camera usage will be allowed in only one area of the hearing room. To provide everyone a chance to speak, public testimony will be limited to 10 minutes per speaker and should be specific to the proposed regulations. Testimony which would exceed 10 minutes may be submitted in writing.

Please note that public comment will begin promptly at 10:00 a.m. and will conclude when the last speaker has finished his or her presentation or 5:00 p.m., whichever is earlier. If public comment concludes before the noon recess, no afternoon session will be held.

The Administrative Director requests, but does not require that, any persons who make oral comments at the hearings also provide a written copy of their comments. Equal weight will be accorded to oral comments and written materials.

ACCESSIBILITY

The State Office Buildings and Auditoriums are accessible to persons with mobility impairments. Alternate formats, assistive listening systems, sign language interpreters, or other type of reasonable accommodation to facilitate effective communication for persons with disabilities, are available upon request. Please contact the Statewide Disability Accommodation Coordinator, Kathleen Estrada, at 1-866-681-1459 (toll free), or through the California Relay Service by dialing 711 or 1-800-735-2929 (TTY/English) or 1-800-855-3000 (TTY/Spanish) as soon as possible to request assistance.

WRITTEN COMMENT PERIOD

Any interested person, or his or her authorized representative, may submit written comments relevant to the proposed regulatory action to the Department of Industrial Relations, Division of Workers' Compensation. The written comment period closes at **5:00 p.m., on Tuesday, January 25, 2011**. The

Department of Industrial Relations, Division of Workers' Compensation will consider only comments received at the Department of Industrial Relations, Division of Workers' Compensation by that time. Equal weight will be accorded to oral comments presented at the hearing and written materials.

Submit written comments concerning the proposed regulations prior to the close of the public comment period to:

Maureen Gray
Regulations Coordinator
Department of Industrial Relations
Division of Workers' Compensation, Legal Unit
Post Office Box 420603
San Francisco, CA 94142

Written comments may be submitted by facsimile transmission (FAX), addressed to the above-named contact person at (510) 286-0687. Written comments may also be sent electronically (via e-mail) using the following e-mail address: dwcrules@dir.ca.gov.

Unless submitted prior to or at the public hearing, Ms. Gray must receive all written comments no later than **5:00 p.m. on Tuesday, January 25, 2011**.

AUTHORITY AND REFERENCE

The Administrative Director is undertaking this regulatory action pursuant to the authority vested in her by Labor Code sections 59, 133, 4603.4, 4603.5, and 5307.3.

Reference is to Labor Code sections 4600, 4603.2, 5307.11 and 5307.1.

INFORMATIVE DIGEST AND POLICY STATEMENT OVERVIEW

Existing law establishes a workers' compensation system, administered by the Administrative Director of the Division of Workers' Compensation, to compensate an employee for injuries sustained in the course of his or her employment. Labor Code section 4600 requires an employer to provide medical, surgical, chiropractic, acupuncture, and hospital treatment, including nursing, medicines, medical and surgical supplies, crutches, and apparatus, including orthotic and prosthetic devices and services, that is reasonably required to cure or relieve the injured worker from the effects of his or her injury. Under existing law, payment for medical treatment shall be no more than the maximum amounts set by the Administrative Director in the Official Medical Fee Schedule or the amounts set pursuant to a contract. Labor Code section 5307.1, as amended by Senate Bill 228 of 2003 (Chapter 639, Statutes of 2003, effective January 1, 2004), requires the Administrative Director to adopt and revise periodically an Official Medical Fee Schedule that establishes the reasonable maximum fees paid for all medical services rendered in workers' compensation cases.

Except for physician services, all fees in the adopted schedule must be in accordance with the fee-related structure and rules of the relevant Medicare (administered by the Center for Medicare & Medicaid Services of the United States Department of Health and Human Services) and Medi-Cal payment systems. Upon adoption by the administrative director of an Inpatient Hospital Official Medical Fee

Schedule the maximum reasonable fees shall not exceed 120 percent of estimated aggregate fees prescribed in the Medicare payment system for the same class of services before application of the inflation factor. (Lab. Code, § 5307.1(a).) The inflation factor is determined solely by the estimated adjustment in the hospital market basket for the 12 months beginning October 1 of the preceding calendar year. (Lab. Code, § 5307.1(g).) The Administrative Director, however, may adopt different conversion factors, diagnostic related group weights, and other factors affecting payment amounts from those used in the Medicare payment system, provided estimated aggregate fees do not exceed 120 percent of the estimated aggregate fees paid for the same class of services in the Medicare Payment System. (Lab. Code, § 5307.1(b).)

In 2003, the legislature enacted Labor Code section 5318, which provided a separate reimbursement for implantable medical devices, hardware, and instrumentation for six different Diagnostic Related Groups (DRGs). The statute also provided that the pass-through section would only be operative until the Administrative Director adopts a regulation specifying separate reimbursement, if any, for implantable medical hardware or instrumentation for complex spinal surgeries. (Lab. Code, § 5307.1(b).)

Labor Code section 5307.1 also provides that the Administrative Director shall adjust the Inpatient Hospital Fee Schedule to conform to any relevant changes in the Medicare payment system by issuing an order, exempt from Labor Code sections 5307.3 and 5307.4 and the rulemaking provisions of the Administrative Procedure Act (Chapter 3.2 (commencing with section 11340) of Part 1 of Division 3 of Title 2 of the Government Code), informing the public of the changes and their effective date. (Lab. Code, § 5307.1(g)(2).)

Effective Jan. 1, 2004, the Administrative Director adopted the Inpatient Hospital Fee Schedule (California Code of Regulations, title 8, sections 9789.20 et seq.), which incorporated the Labor Code section 5318 pass-through, which is updated annually by Administrative Director Order.

The Administrative Director now proposes to amend sections 9789.20 through 9789.22 which revises the methodology for separate reimbursement of implantable spinal hardware used in complex spinal surgeries, and proposes minor amendments to conform to the proposed changes, to update, or to clarify sections of the Inpatient Hospital Fee Schedule. The Administrative Director also proposes to adopt section 9789.25 which provides for the updates to the federal regulation, federal register, and payment impact file references made in the Inpatient Hospital Fee Schedule updates by Order of the Administrative Director, in order to conform to changes in the Medicare payment system as required by Labor Code section 5307.1.

The proposed regulations implement, interpret, and make specific sections 4600, 5307.1, and 5318 of the Labor Code as follows:

1. Section 9789.20 – General Information for Inpatient Hospital Fee Schedule – Discharge on or After July 1, 2004

Subdivision (c) is amended to add the proposed section 9789.25 to the Inpatient Hospital Fee Schedule section of the Official Medical Fee Schedule.

Subdivision (d) is amended to change the effective date for annual updates to the Inpatient Hospital Fee Schedule from October 1 to December 1 of each year, to provide for a more realistic effective date given the constraints of when the Medicare publishes the final rule and to provide adequate notice (30-

days) to affected parties. Since 2004, depending on the year, Medicare has published its final rule as early as August 1st and as late as August 27th, with an effective date of October 1st. It is not unusual for Medicare to publish notices and corrections to its final rule after the final rule is published. In order to give adequate notice (30 days) to affected parties, the current effective date of October 1 is unachievable. The proposed effective date is in conformance with Labor Code section 5307.1(g)(1)(A), which states in pertinent part, “Notwithstanding any other provision of law, the official medical fee schedule shall be adjusted to conform to any relevant changes in the Medicare and Medi-Cal payment systems no later than 60 days after the effective date of those changes...”.

2. Section 9789.21 – Definitions for Inpatient Hospital Fee Schedule

The Administrative Director’s Orders updating the Inpatient Hospital Fee Schedule pursuant to Labor Code section 5307.1(g)(2) are now organized and referenced in section 9789.25, and therefore are deleted from this section. Specifically, references to the federal regulation, federal register, and payment impact file made in subdivisions (b)(1), (b)(2), (b)(3), (d now e)(1)(B now C), (d now e)(1)(C now D), (d now e)(1)(D now E), (d now e)(1)(E now F), (d now e)(1)(F now G), (d now e)(2)(B), (d now e)(2)(C), (d now e)(2)(E), (d now e)(2)(F), (d now e)(2)(G), (f), (o), (q now r)(1)), (s now t) are organized and moved to section 9789.25, and deleted from this section.

Subdivision (b) is amended to clarify the effective date of discharge when choosing the formula used to arrive at the capital outlier factor. For discharges occurring on or after January 1, 2004 and before January 1, 2008, a large urban add-on is applied. The large urban add-on was eliminated for discharges on or after January 1, 2008. Subdivision (b), second paragraph is amended to substitute the word “of” with the word “to” in the last sentence of the paragraph.

Subdivision (d), is added to define “Complex spinal surgery”. The current regulation lists complex spinal surgery DRGs in sections 9789.22(e) and (f). Complex spinal surgery is entitled to an additional payment allowance pursuant to section 9789.22.

Subdivision (d now e) is amended to: 1. exclude payments for spinal hardware used in complex spinal surgery in addition to payments for outlier cases and new technology when calculating the composite factor; 2. clarify that composite factor means the standard OMFS rate for a hospital; 3. clarify that the prospective operating costs are hospital-adjusted; and 4. substitute “hospital” for “health facility” to conform to the changes made to section 9789.21(l).

Subdivision (d now e)(1) is amended to clarify that the prospective capital costs are hospital-adjusted.

Subdivision (d now e)(1)(A) is amended to clarify the effective date of discharge when choosing the formula used to arrive at the hospital-adjusted rate for prospective capital costs. For discharges on or after January 1, 2004 and before January 1, 2008, a large urban add-on is applied when arriving at the hospital-adjusted rate for prospective capital costs. The large urban add-on was eliminated for discharges on or after January 1, 2008. This subdivision is amended to clarify that the prospective capital costs are hospital-adjusted; and to correct the term “Capital standard payment rate” to “Capital standard federal payment rate.”

Subdivision (d now e)(1)(B) adds the definition of “capital market basket” to mean the Medicare capital input price index (CIPI) and the capital standard federal payment rate is the capital market basket applied to the capital standard federal payment rate for the preceding period. This definition was inadvertently omitted from the current regulation.

Subdivision (d now e)(1)(C) is re-lettered subdivision e(1)(C). The subdivision is further amended to clarify that for each update in the composite factor, the capital standard federal payment rate for the preceding period is adjusted by the rate of change in the capital market basket.

Subdivision (d now e)(2) is amended to clarify that the prospective operating costs are hospital-adjusted.

Subdivision (d now e)(2)(A) is amended to: 1. clarify that the prospective operating costs are hospital-adjusted; 2. correct the wage-adjusted standard rate formula by substituting “labor-related national” for “OMFS”; and 3. clarify the formula used to calculate the hospital-adjusted rate for prospective operating costs is in conformance with California Labor Code section 5307.1(g)(1)(A)(i).

Subdivision (d now e)(2)(B) is amended to clarify that for each update in the composite factor, the labor-related national standardized amount for the preceding period is adjusted by the rate of change in the operating market basket. The subdivision is further amended to reference section 9789.25(b) for the labor-related national standard operating rate for discharges occurring on or after November 29, 2004 by date of discharge.

Subdivision (d now e)(3) is amended to substitute “hospital” for “health facility” to conform to changes made to section 9789.21(l), and to make a minor formatting change.

Subdivision (e) “Costs” is rescinded because section 9789.22(f) provides formulas used to determine costs.

Subdivision (g) is amended to reflect the rescission of Subdivision (e).

Subdivision (h) is amended to include additional allowance for spinal hardware under section 9789.22(g) or (h) in calculating the cost outlier threshold, and substitutes “Section 9789.22(g)” for “subdivision (j)” to conform to the numbering changes.

Subdivision (l) is amended to change the term from “health facility” to “hospital” for clarity. Where used in this fee schedule, the term “hospital” is substituted for “health facility”.

Subdivision (m) is amended to substitute “hospital” for “health facility” to conform to the changes made to section 9789.21(l).

Subdivision (n) is amended to conform to changes made to the payment methodology for complex spinal surgery cases.

Subdivision (p) is added to define “large urban add-on” as it is used in the Inpatient Hospital Fee Schedule.

Subdivision (q now r) is amended to clarify the labor-related portion is applied to the operating wage index when calculating the operating outlier factor.

Subdivision (r now s) is amended to substitute “hospital” for “health facility” to conform to the changes made to section 9789.21(l).

Subdivision (u) is added to define “price adjustment” as any and all price reductions, offsets, discounts, rebates, adjustments, and or refunds which accrue to or are factored into the final net cost to the hospital. Where used in this fee schedule, the term “price adjustment” is substituted for “discounts and rebates” for clarification.

Subdivision (w) is added to define “spinal hardware”. A definition of spinal hardware was previously defined in section 9789.22(f) as a “device”. Subdivision (w) substitutes “spinal hardware” for “device”, and refines the definition to clarify spinal hardware is a permanently implantable device surgically implanted, embedded, inserted, or otherwise applied to a human body in the course of complex spinal surgery. The device must be intended to function for more than one year and throughout the useful life of the device, to assist, restore, or replace, or otherwise therapeutically influence the function of the spine. The term, spinal hardware, does not apply to any device which is intended for temporary purposes or intended for removal. The device must be recognized in the official United States Pharmacopoeia-National Formulary, or any supplement to it, and be reasonably required to cure or relieve the injured worker from the effects of his or her injury pursuant to Labor Code section 4600.

3. Section 9789.22. Payment of Inpatient Hospital Services

Subdivision (a) is amended to conform to changes made to the payment methodology for complex spinal surgery cases proposed in sections 9789.22(f)(2), (g), and (h) and substitutes “hospital” for “health facility” to conform to changes made to section 9789.21(l).

Subdivision (c) is amended to make a minor formatting change.

Subdivision (d) is added to clarify that professional services are paid under a separate Official Medical Fee Schedule (beginning at section 9789.10) and to clarify that billing for payment under the Inpatient Hospital Fee Schedule shall originate from hospitals and payment may be made only to hospitals for covered items and services including any spinal hardware separately payable under section 9789.22(g) or (h).

Subdivision (d now e) is amended to conform to changes made to the payment methodology for complex spinal surgery cases, and substitutes “hospital” for “health facility” to conform to section 9789.21(l). This amendment requires, when applicable, documentation of the costs of implanted spinal hardware be submitted in accordance with section 9789.22(h).

Subdivision (e now f)(1 through 4) is amended to change the numbering within the subdivision.

Subdivision (e now f)(5) is rescinded because “complex spinal surgery” DRGs are now defined in section 9789.21(d) and listed by date of discharge in section 9789.25(b).

Subdivision (e now f)(1) is amended to define the formula used to calculate additional allowance for cost outlier cases exclusive of complex surgery cases involving spinal hardware reimbursed under section 9789.22(h). The higher costs for cost outlier cases that do not involve complex spinal surgery reimbursed under section 9789.22(h) shall be reimbursed as follows:

Step 1: Determine the Inpatient Hospital Fee Schedule maximum payment amount (DRG weight x 1.2 x hospital specific composite factor).

Step 2: Determine costs. $\text{Costs} = (\text{total billed charges} \times \text{total cost-to-charge ratio})$.

Step 3: Determine outlier threshold. $\text{Outlier threshold} = (\text{Inpatient Hospital Fee Schedule payment amount} + \text{hospital specific outlier factor} + \text{any new technology pass-through payment determined under section 9789.22(j)})$.

If costs exceed the outlier threshold, the case is a cost outlier case. The additional allowance for the outlier case equals $0.8 \times (\text{costs} - \text{outlier threshold})$.

Subdivision (e now f)(2) is added to define the formula used to calculate additional allowance for cost outlier cases involving complex spinal surgery cases. The higher costs of a case involving spinal hardware reimbursed under section 9789.22(h) shall be reimbursed using the following method. This method is optional for other cases involving complex spinal surgery and may be elected by a hospital on a case-by-case basis in lieu of the method in section 9789.22(f)(1). A hospital electing this method for other complex spinal surgery cases must document the cost of any spinal hardware as required under section 9789.22(h). The method is as follows:

Step 1: Determine the Inpatient Hospital Fee Schedule maximum payment amount ($\text{DRG weight} \times \text{hospital specific composite factor} \times \text{applicable multiplier}$).

Step 2: Determine total costs. $\text{Total Costs} = (\text{total charges} - \text{charges for any spinal hardware}) \times (\text{total cost-to-charge ratio}) + \text{documented paid cost of any spinal hardware, plus an additional 10\% of the hospital's documented paid cost, net of immediate and anticipated price adjustments, not to exceed a maximum of \$250.00, plus any sales tax and/or shipping and handling charges actually paid.}$

Step 3: Determine outlier threshold. $\text{Outlier threshold} = (\text{Inpatient Hospital Fee Schedule payment amount} + \text{hospital specific outlier factor} + \text{any additional allowance for spinal hardware under section 9789.22(g) or (h)} + \text{any new technology pass-through payment determined under section 9789.22(j)})$. If costs determined in Step 2 exceed the outlier threshold, the case is a cost outlier case. The additional allowance for the outlier case equals $0.8 \times (\text{costs} - \text{cost outlier threshold})$.

Subdivision (f) is rescinded and is replaced with subdivisions (g) and (h), which define how additional allowance for spinal hardware used in complex spinal surgery is provided for. The DRGs that define complex spinal surgeries have been moved to the definition section (section 9789.21(d)), and the definition of “device” is changed to “spinal hardware” and also moved to the definition section (section 9789.21(w)).

Subdivision (g) is added to provide the method of determining additional allowance for spinal hardware used in complex spinal surgery unless the hospital makes a one-time annual election for an alternative maximum payment allowance and additional allowance for spinal hardware used in complex spinal surgery under Subdivisions (h) and (i). For discharges occurring before December 15, 2010, costs for spinal hardware used during complex spinal surgery shall be separately reimbursed at the hospital's documented paid cost, plus an additional 10% of the hospital's documented paid cost, net of price adjustments, not to exceed a maximum of \$250.00, plus any sales tax and/or shipping and handling charges actually paid. For discharges occurring on or after December 15, 2010, an additional allowance of \$2,925 shall be made for discharges assigned to MS-DRGs 453, 454, 455, 456, 457, 458, 459, and 460 and an additional allowance of \$625 shall be made for discharges assigned to MS-DRGs 028, 029, 030, 471, 472, and 473. Effective with each update in the composite rate, the additional allowance in section 9789.22(g)(2)(A) shall be adjusted by the rate of change in the hospital operating market basket.

Subdivision (h) is added to provide an alternate payment method for discharges assigned only to complex spinal surgery cases in lieu of the Inpatient Hospital Fee Schedule maximum payment allowed under section 9789.22(a) and additional allowance under section 9789.22(g)(2). The hospital may make

one annual election encompassing all complex spinal surgery cases pursuant to section 9789.22(i) for an alternate maximum payment allowance and additional allowance to be determined as follows:

Multiplier x DRG weight x hospital specific composite factor plus the additional allowance for documented paid cost for spinal hardware, plus an additional 10% of the hospital's documented paid cost, net of immediate and anticipated price adjustments, not to exceed a maximum of \$250.00, plus any sales tax and/or shipping and handling charges actually paid.

The multiplier shall be as follows: For discharges occurring on or after December 15, 2010, the multiplier shall be 1.0. For discharges occurring on or after the effective date of the 2012 annual update, the multiplier shall be 0.8.

The hospital shall submit documentation that includes for each spinal hardware item: (1) a description; (2) the name of the manufacturer, the manufacturer's supply code, and the item's unique identifier; (3) the charge included in the hospital's bill; (4) the hospital's documented paid cost net of immediate price adjustments and anticipated price adjustments based upon the hospital's prior calendar year's usage for comparable spinal hardware; and (5) any sales tax and/or shipping and handling charges actually paid. The operative report of the patient's medical record must be submitted by the hospital and clearly document the spinal hardware items that were implanted for each discharge, and a responsible hospital official shall certify that the documentation accurately reflects the complete list of spinal hardware items utilized for the patient and accurately reflects the patient's spinal hardware costs by including the following sentence: "I hereby certify under penalty of perjury that the following is the true and correct actual cost and list of the items meeting the criteria in Title 8, California Code of Regulations section 9789.22(h)."

Subdivision (i) is added to set forth the requirements a hospital needs to meet in order to make an annual election of the alternate allowance methodology set forth in section 9789.22(h). The election must be submitted in writing to the Administrative Director and postmarked by December 15 of each year. The election shall be effective for one year commencing with discharges on or after January 1 following the month of December in which the election is made. If the hospital does not file a timely election, the maximum payment allowed to a hospital shall be determined under section 9789.22(a) and additional allowance for spinal hardware used in complex spinal surgery shall be determined under section 9789.22(g)(2). Before January 1 of each year the Administrative Director shall post a list of those hospitals electing to be paid under the alternate payment method set forth in section 9789.22(h).

Subdivisions (g now j), (h now k), (i now l)(2)(A), (i now l)(2)(B), (j now m)(3), and (j now m)(5) are amended to move references to the federal regulation, federal register, and payment impact file made in the inpatient hospital fee schedule updates by Order of the Administrative Director, to section 9789.25.

Subdivision (i now l)(1) is amended to: 1. substitute "hospital" for "health facility" to conform to changes made to section 9789.21(l); 2. conform to the changes made to the payment methodology for complex spinal surgery cases; and 3. minor formatting changes. This amendment provides the first day of the stay in the transferring hospital shall be reimbursed at twice the per diem amount and the hospital shall receive the additional allowances under either sections 9789.22(g) or (h) and under section 9789.22(j) when applicable.

Subdivisions (i now l)(2), (i now l)(2)(A), (i now l)(2)(B), and (j now m) are amended to make minor changes to formatting and citations to conform to changes made in this regulation.

Subdivision (k now n) is amended to substitute “hospital” for “health facility” to conform to changes to section 9789.21(1). This amendment also requires submittal of different information for discharges occurring on or after December 15, 2010, when a hospital is not listed in section 9789.23, requests the Administrative Director to provide a hospital specific composite factor or hospital specific outlier factor. The hospital will be required to provide in writing the following Medicare information: Medicare provider number, physical location, county code, hospital specific operating and capital CCRs, and DSH and/or IME adjustments, if applicable.

Subdivision (l now o) is amended to substitute “hospital” for “health facility” to conform to changes to section 9789.21(1).

4. Section 9789.25. Federal Regulations, Federal Register Notices, and Payment Impact File by Date of Discharge.

This section is added to provide the updates to the federal regulation, federal register, and payment impact file references made in the Inpatient Hospital Fee Schedule updates by Order of the Administrative Director, in order to conform to changes in the Medicare payment system as required by Labor Code section 5307.1(g)(2).

Subdivision (a) lists the federal regulations by date of discharge that are referenced in the Inpatient Hospital Fee Schedule updates and are incorporated by reference.

Subdivision (b) lists the federal register notices by date of discharge that are referenced in the Inpatient Hospital Fee Schedule updates and are incorporated by reference.

Subdivision (c) lists the payment impact file by date of discharge referenced in the Inpatient Hospital Fee Schedule updates and are incorporated by reference.

DISCLOSURES REGARDING THE PROPOSED REGULATORY ACTION

The Administrative Director has made the following initial determinations:

- Significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states: None. Adoption of these regulations will only reduce the amount of duplicate payment currently being made for the spinal hardware used in complex spinal surgery.
- Adoption of these regulations will not: (1) create or eliminate jobs within the State of California, (2) create new businesses or eliminate existing businesses within the State of California, or (3) affect the expansion of businesses currently doing business in California.
- Effect on Housing Costs: None.
- The Division of Workers’ Compensation is aware of cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the

proposed action. The proposed regulations will most significantly affect hospitals, workers' compensation insurers, self-insured employers and workers' compensation third party administrators.

The Medicare fee related payment structure is based on the averaging concept, so that in some cases the hospitals may be paid less than cost and in other cases the hospital may be paid more than cost. But, on the average, the allowance should be reasonable.

- The proposed adoption of section 9789.22(f)(2), additional allowance for cost outlier cases involving complex spinal surgery, addresses the concern that "charge compression" will adversely affect when a complex spinal surgery case would be eligible for an additional cost outlier payment, as well as determining the amount of the additional payment. Charge compression typically occurs when calculating the overall cost-to-charge ratio for a hospital, because hospitals tend to have lower mark-up on high cost items such as spinal hardware and have higher mark-up on low cost items. This has resulted in costs being understated by approximately 13 to 15 percent in complex spinal surgeries which use spinal hardware due to charge compression. The proposed amendment removes the charge compression factor when determining whether a complex spinal surgery case is a cost outlier case and provides for a more accurate calculation of the amount of additional payment to the hospital.
- The proposed adoption of sections 9789.22(g) and (h) will reduce the amount of duplicate payment for spinal hardware used in complex spinal surgeries by an estimated \$28 million in 2011 and an estimated \$55 million in 2012. The duplicate payment for spinal hardware in the current regulation is the amount paid for in both the standard rate of payment for complex spinal surgery cases and again in the pass-through provision which pays for the documented cost of the spinal hardware. In other words, the standard payment (1.20 x Medicare payment) already account for significant device costs in complex spinal surgery DRGs. Using MS-DRG 460 (spinal fusion except cervical without MCC) as an example, device and non-device costs (before adjustment for charge compression) account for 47.2 percent and 52.8 percent, respectively, of the average Medicare cost per discharge. As stated earlier, current policy allows an additional payment for spinal hardware at the documented cost.

The proposed addition of sections 9789.22(g) and (h) will provide for the following: Hospitals will have an annual choice in how they would be reimbursed for complex spinal surgery using permanently implantable hardware. Hospitals may choose between two alternatives, either: 1. section 9789.22(g) - The standard hospital-specific MS-DRG reimbursement (1.2 x MS-DRG weight x hospital specific composite factor) plus an additional allowance of \$2,925 for discharges assigned to MS-DRGs 453, 454, 455, 456, 457, 458, 459 and 460; and an additional allowance of \$625 for discharges assigned to MS-DRGs 028, 029, 030, 471, 472, and 473 for hardware used in complex spinal surgery; or 2. section 9789.22(h) - The alternate payment methodology will be a multiplier of the hospital-specific MS-DRG reimbursement, plus the documented invoice cost of the hardware used in complex spinal surgery. The multiplier will be 1.0 for discharges occurring in the first year of the revised fee schedule and 0.8 for discharges occurring on or after the effective date for the 2012 annual update. The hospital will be required to submit a detailed invoice pertaining to the implanted hardware accompanied

with a certification attesting to the accuracy of the cost of the items.

Payment under section 9789.22(g) will reduce administrative burden to hospitals, workers' compensation insurers, self-insured employers, and workers' compensation third party administrators, relative to the current payment policy. No invoices are needed, and do not require knowing the spinal hardware costs and usage. This payment methodology also recognizes some variation in costs of the spinal hardware used in a complex spinal surgery.

Payment under section 9789.22(h) recognizes variation in usage, and provides for the greatest payment accuracy since payment is based on actual hardware costs. However, this method of payment will continue the administrative burden at current levels.

It is difficult to estimate the impact on individual hospitals, as they will vary greatly depending on which annual method of payment is selected by the hospital, and the volume and mix of complex spinal surgeries performed at the hospital. An analysis by Barbara O. Wynn, RAND, however, estimates that in 2011, 152 out of 163 hospitals will receive a higher payment under the alternate payment method (section 9789.22(h)) than under the add-on allowance prescribed by section 9789.22(g). In 2012, approximately 102 out of 163 hospitals are projected to receive a higher payment on average under the alternate payment method than under the add-on allowance method. If the hospital elects payment for complex spinal surgery under section 9789.22(g), the hospital should receive reasonable payment with little additional administrative burden, if at all. If the hospital elects payment under section 9789.22(h), there will be increased accuracy in payment to the hospital because payment will be based on documented costs of the spinal hardware.

Workers' compensation insurers, self-insured employers and workers' compensation third party administrators, will benefit with less administrative burden and, overall, the amount of duplicate payment for spinal hardware should be reduced.

EFFECT ON SMALL BUSINESS

The Administrative Director has determined that the proposed regulations will affect small business as all California employers who are required to have workers' compensation will have reduced costs for spinal hardware used in complex spinal surgery procedures.

FISCAL IMPACTS

- Costs or savings to state agencies: These regulations affect the State Compensation Insurance Fund (SCIF), which is the largest workers' compensation insurer in the state. In 2008, SCIF had 22.6% of the workers' compensation market share (p.49, 2008 *California Property and Casualty Market Share Report*, CA Dept. of Insurance, <http://www.insurance.ca.gov/0400-news/0200-studies-reports/0100-market-share/Marketshare2008/upload/IndMktShr2008WP.pdf>). Reducing the amount of duplicate payment for spinal hardware used in complex spinal surgeries will reduce the cost to SCIF from an estimated \$6m to \$11m. In addition, the administrative costs will decrease when payment is made to hospitals that elect the add-on amount for spinal hardware (section 9789.22(g)).

- Costs/savings in federal funding to the State: None.
- Local Mandate: None. The proposed regulations will not impose any new mandated programs or increased service levels on any local agency or school district. The potential costs imposed on all public agency employers by these proposed regulations, although not a benefit level increase, are not a new State mandate because the regulations apply to all employers, both public and private, and not uniquely to local governments. The Administrative Director has determined that the proposed regulations will not impose any new mandated programs on any local agency or school district. The California Supreme Court has determined that an increase in workers' compensation benefit levels does not constitute a new State mandate for the purpose of local mandate claims because the increase does not impose unique requirements on local governments. See *County of Los Angeles v. State of California* (1987) 43 Cal.3d 46. The potential costs imposed on all public agency employers and payors by these proposed regulations, although not a benefit level increase, are similarly not a new State mandate because the regulations apply to all employers and payors, both public and private, and not uniquely to local governments.
- Cost to any local agency or school district that is required to be reimbursed under Part 7 (commencing with section 17500) of Division 4 of the Government Code: None. The proposed regulations do apply to a local agency or school district in its capacity as an employer required to provide workers' compensation benefits to injured workers.
- Other nondiscretionary costs/savings imposed upon local agencies: None.

CONSIDERATION OF ALTERNATIVES

The Administrative Director will be responsible for determining that no reasonable alternative considered or that has otherwise been identified and brought to the Administrative Director's attention would be more effective in carrying out the purpose for which the actions are proposed or would be as effective and less burdensome to affected private persons than the proposed actions.

The Administrative Director invites interested persons to present statements or arguments with respect to alternatives to the proposed regulations at the scheduled hearing or during the written comment period.

PUBLIC DISCUSSIONS OF PROPOSED REGULATIONS

A text of draft proposed regulations was made available for pre-regulatory public comment through the Division's Internet message board (the DWC Forum.) Additionally, pre-rulemaking stakeholder's meetings were held over a period of nine months to receive input on the development of the regulations.

AVAILABILITY OF INITIAL STATEMENT OF REASONS, TEXT OF PROPOSED REGULATIONS, RULEMAKING FILE AND DOCUMENTS SUPPORTING THE RULEMAKING FILE / INTERNET ACCESS

An Initial Statement of Reasons and the text of the proposed regulations in plain English have been prepared and are available from the contact person named in this notice. The entire rulemaking file will be made available for inspection and copying at the address indicated below. However, documents subject to copyright may be inspected but not copied.

As of the date of this notice, the rulemaking file consists of the notice; the initial statement of reasons; the proposed text of the regulations (underline and strikeout version and clean version); the documents incorporated by reference; and the Form 399, Economic and Fiscal Impact Statement. Also included are studies and documents relied upon in drafting the proposed regulations and Form 399, Economic and Fiscal Impact Statement.

In addition, the Notice, Initial Statement of Reasons, and proposed text of regulations may be accessed and downloaded from the Division's website at www.dir.ca.gov. To access them, click on the link for the Division of Workers' Compensation homepage, then click on the "Participate in Rulemaking" link and scroll down the list of rulemaking proceedings to find the current Inpatient Hospital Fee Schedule rulemaking link.

Any interested person may inspect a copy or direct questions about the proposed regulations and any supplemental information contained in the rulemaking file. The rulemaking file will be available for inspection at the Department of Industrial Relations, Division of Workers' Compensation, 1515 Clay Street, 18th Floor, Oakland, California, between 9:00 a.m. and 4:30 p.m., Monday through Friday, unless the state office is closed for a state holiday or furlough (which is generally the second, third, and fourth Friday of each month.). Copies of the proposed regulations, initial statement of reasons and any information contained in the rulemaking file may be requested in writing to the contact person.

CONTACT PERSON

Nonsubstantive inquiries concerning this action, such as requests to be added to the mailing list for rulemaking notices, requests for copies of the text of the proposed regulations, the Initial Statement of Reasons, and any supplemental information contained in the rulemaking file may be requested in writing at the same address. The contact person is:

Maureen Gray
Regulations Coordinator
Department of Industrial Relations
Division of Workers' Compensation
Post Office Box 420603
San Francisco, CA 94142
E-mail: mgray@dir.ca.gov

The telephone number of the contact person is (510) 286-7100.

BACKUP CONTACT PERSON / CONTACT PERSON FOR SUBSTANTIVE QUESTIONS

In the event the contact person is unavailable, or to obtain responses to questions regarding the substance of the proposed regulations, inquiries should be directed to the following backup contact person:

Minerva Krohn, Industrial Relations Counsel IV or
Jarvia Shu, Industrial Relations Counsel III
Department of Industrial Relations
Division of Workers' Compensation
Post Office Box 420603
San Francisco, CA 94142
E-mail: (mkrohn@dir.ca.gov; jshu@dir.ca.gov)

The telephone number of the backup contact persons is (510) 286-7100.

AVAILABILITY OF CHANGES FOLLOWING PUBLIC HEARING

If the Administrative Director makes changes to the proposed regulations as a result of the public hearing and public comment received, the modified text with changes clearly indicated will be made available for public comment for at least 15 days prior to the date on which the regulations are adopted.

AVAILABILITY OF THE FINAL STATEMENT OF REASONS

Upon its completion, the Final Statement of Reasons will be available and copies may be requested from the contact person named in this notice or may be accessed on the website: www.dir.ca.gov, then click on the link for the Division of Workers' Compensation homepage, then click on the "Participate in Rulemaking" link and scroll down the list of rulemaking proceedings to find the current Inpatient Hospital Fee Schedule rulemaking link.

AUTOMATIC MAILING

A copy of this Notice will automatically be sent to those interested persons on the Administrative Director's mailing list.

If adopted, the regulations as amended and adopted will appear in title 8, California Code of Regulations, commencing with section 9789.20.